

# **Food and Drug Administration**



## **FDA Electronic Submissions Gateway Tutorial** **WebTrader Hosted Solution (WTHS):** **Making Electronic Submissions**

Document Version Date: 04/28/2014

## **1. OVERVIEW**

Organizations looking to utilize the Food and Drug Administration (FDA) Electronic Submissions Gateway (ESG) may not have the technical expertise, infrastructure or the resources required to setup and maintain the ESG WebTrader application. As such, the FDA has developed a WebTrader Hosted Solution (WTHS). The WTHS will:

- Be a cost effective solution for users who do not submit a large volume of electronic documents to the FDA Gateway.
- Resolve software incompatibility issues for small organizations without an IT infrastructure or IT support.

The intended audience of this document is the Industry Testers, FDA WTHS Project Team and any Stakeholder whose input/approval into the WTHS testing is needed.

### **1.1 Purpose**

This tutorial is intended for WTHS users. This tutorial explains how to log into and use the WTHS to make electronic submissions via the ESG to the FDA.

### **1.2 Responsibilities**

This FDA will maintain this document and is responsible for updating this document as the WTHS and WebTrader are updated.

### **1.3 Requirements**

In order to make submissions using the WTHS, users must have the following:

- Submitted a Letter of Non-Repudiation.
- Been approved for a WTHS account.
- If submitting in Test, been approved for a WebTrader Test account.
- If submitting in Production, been approved for a WebTrader Production account.

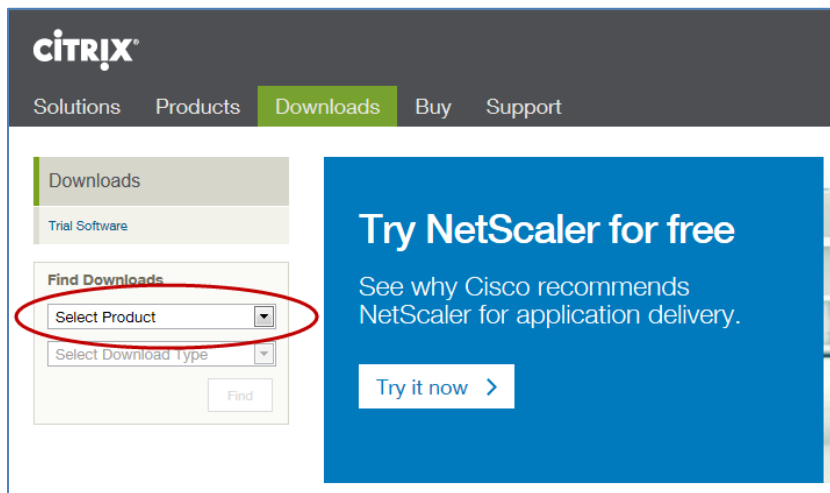
## 2. WTHS PLUGIN INSTALL

Before using the WebTrader Hosted Solution (WTHS,) you must install a Citrix plugin. The following steps are instructions for downloading the Citrix plugin to be used with the WTHS. The download will not require administrative rights to your computer:

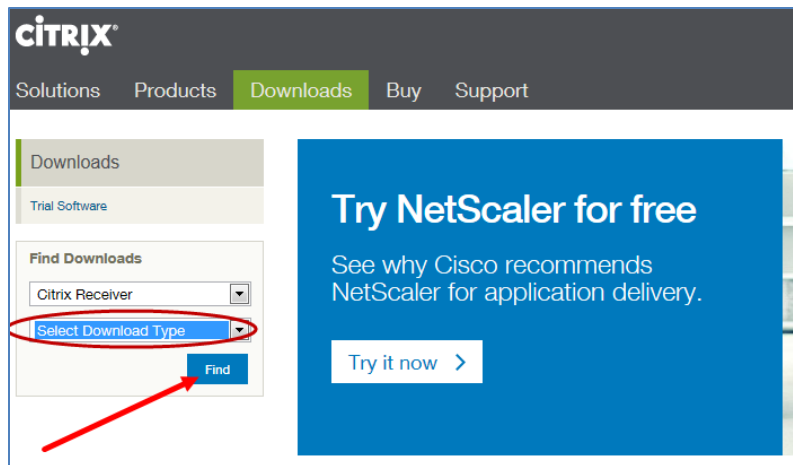
1. Go to <https://esghosted.fda.gov/> .
2. Check the license agreement box and click install.



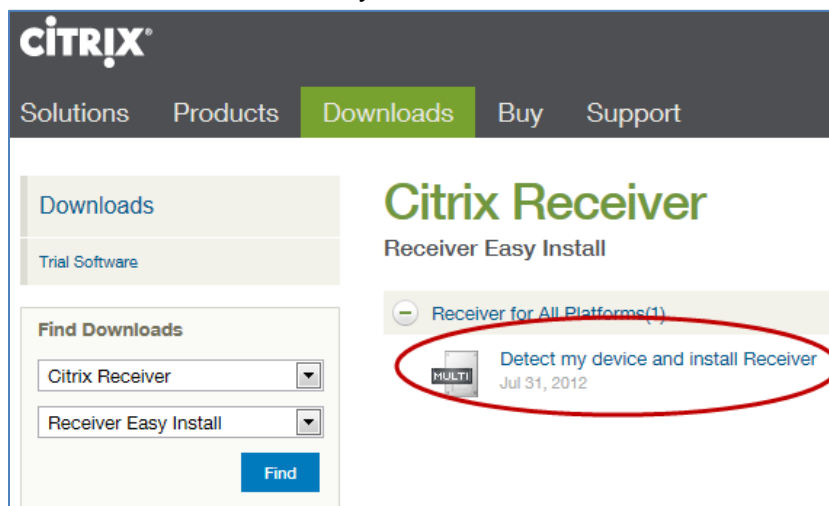
3. In the Select Product drop down menu, select "Citrix Receiver".



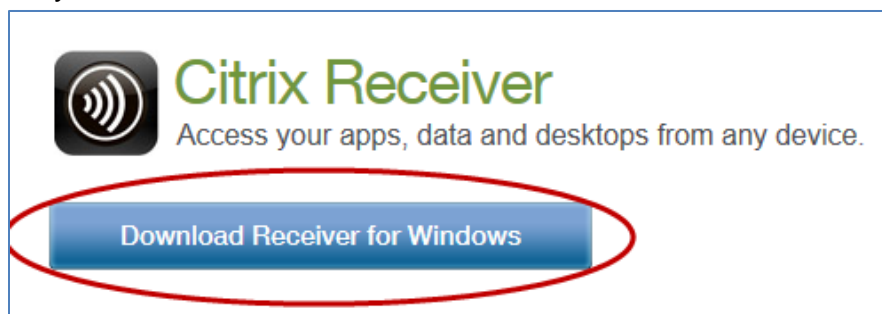
4. In the Select Download Type drop down menu, select "Receiver Easy Install" and click the Find button.



5. Click on the Detect my device and install Receiver.



6. Citrix will determine the appropriate application for you to install and display it on your screen. Click the blue download button.



7. Check "I agree to the terms of the Citrix License Agreement" and click the Continue button.

## Citrix License Agreement

Use of this Citrix Receiver software is subject to the Citrix license covering the specific edition of the Citrix product with which you will be using this software. Your use of Citrix Receiver is limited to use on the devices for which it was created for connection to the Citrix product(s). If your device is connected to the Internet, Citrix Receiver may, without additional notice, check for Citrix Receiver updates that are available for download and installation to your device and let you know of their availability. Only non-personally identifiable information is transmitted when this happens, except to the extent that IP addresses may be considered personally identifiable in some jurisdictions. The use of such information, including your IP address, is governed by the Citrix Privacy Policy available on [www.citrix.com](http://www.citrix.com). Updates will not be downloaded or installed without your consent.

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☒ I agree to the terms of the Citrix License Agreement

Continue

8. Click the Run button. The file is approximately 50 MB and may take a few minutes to download. This is a one-time installation and will not need to be downloaded again.



9. Click the install button and follow installation instructions.



### 3. WTHS INSTRUCTIONS

The following steps are instructions for making electronic submissions in the WebTrader Hosted Solution (WTHS):

1. Go to <https://esghosted.fda.gov/> .
2. Insert WTHS (Citrix) User name and Password.



3. Click Log On button.
4. Click on the ESG-Prod if you wish to make production submissions.

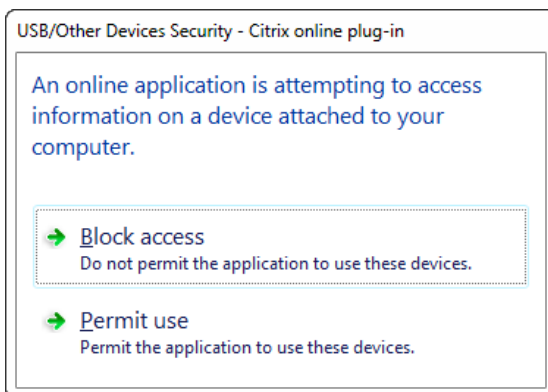


5. Click OK button on Windows Logon window.



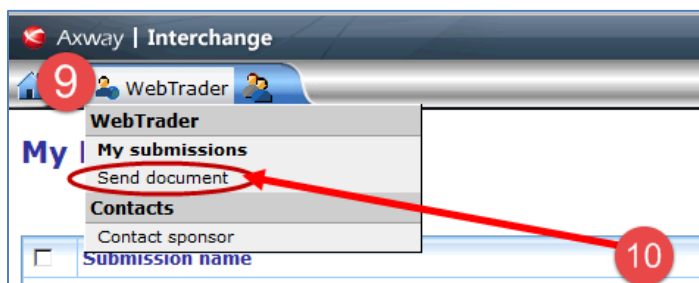
6. If you have USB devices (tablets, phones, etc.) plugged into your machine, you may be prompted with the following window.

- a. If the file you wish to submit is on a USB device, click Permit use.
- b. If the file you wish to submit is NOT on a USB device, you may wish to click Block access.

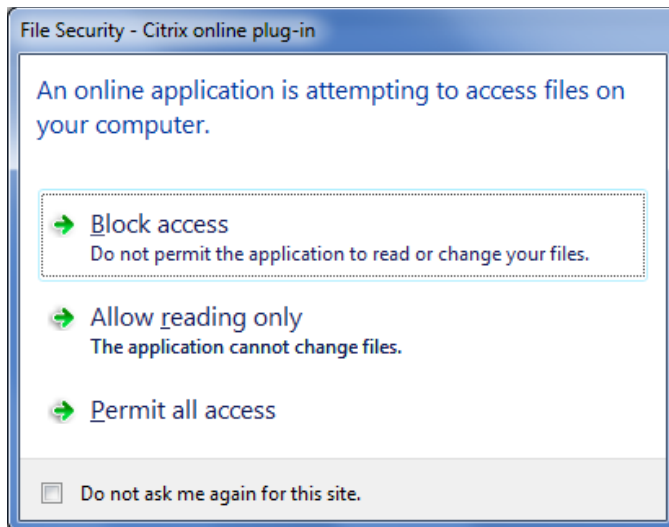


7. Insert WebTrader User ID and Password.

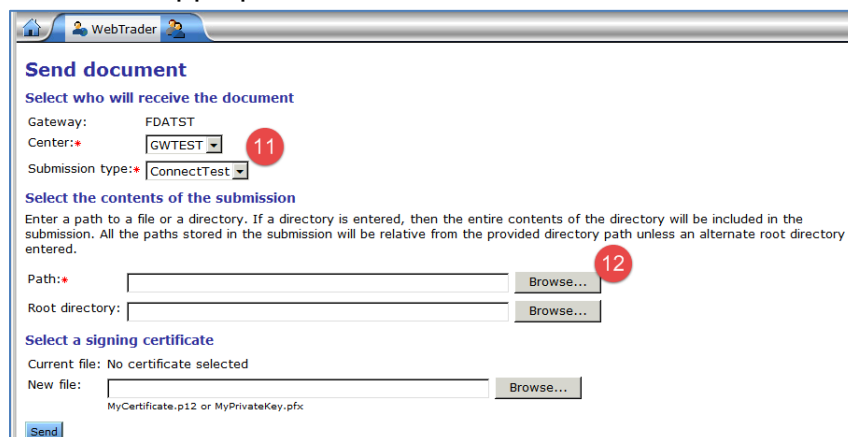
8. Click the Log In button.
9. Hover, but do NOT click on the WebTrader menu at the top of the screen.



10. When selecting a file for submission, you will be prompted with the below pop up window. Click **Permit all access**. You may also wish to check “Do not ask me again for this site” to prevent this pop up in the future:

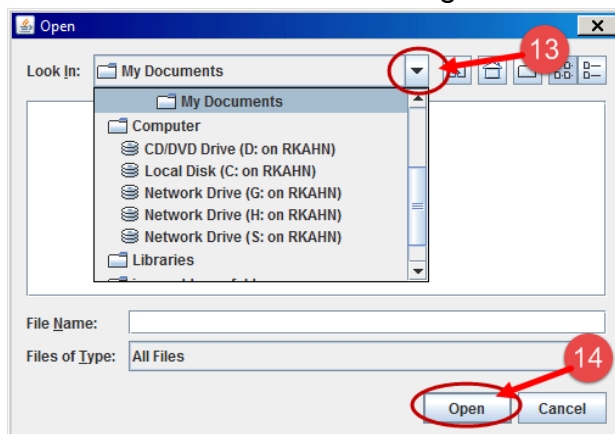


11. Select the appropriate Center and Submission.



12. To the right of the Path field, click the Browse button to select the file to be submitted.

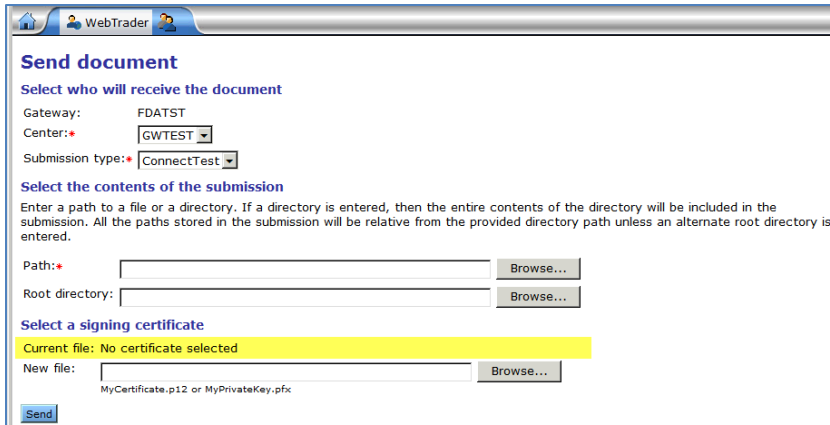
13. Select the down arrow to the right of the "Look In" section.



14. Select the file to be submitted and click the Open button.

15. If no signing certificate is assigned in the highlighted section below, click the Browse button.





**Send document**

Select who will receive the document

Gateway: FDATST  
Center: GWTEST  
Submission type: ConnectTest

Select the contents of the submission

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

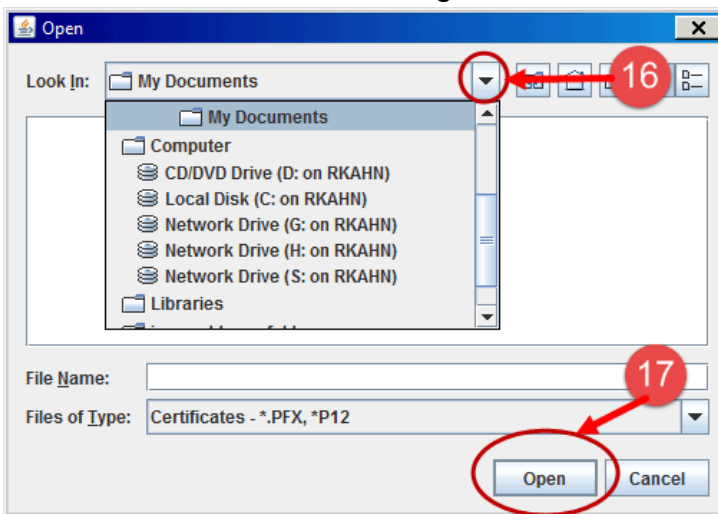
Path:  Browse...  
Root directory:  Browse...

Select a signing certificate

Current file: No certificate selected  
New file:  Browse...  
MyCertificate.p12 or MyPrivateKey.pfx

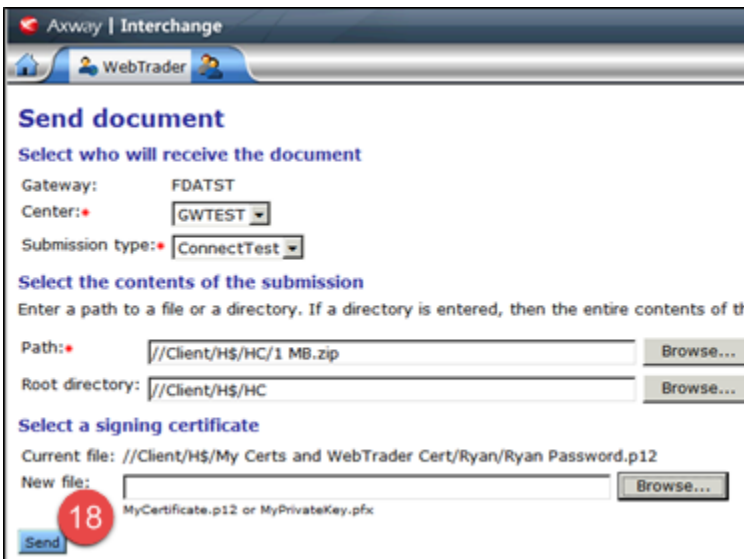
Send

16. Select the down arrow to the right of the "Look In" section.



17. Select the file to be submitted and click the Open button.

18. To submit the file, click the Send button.



**Send document**

Select who will receive the document

Gateway: FDATST  
Center: GWTEST  
Submission type: ConnectTest

Select the contents of the submission

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path: //Client/H\$/HC/1 MB.zip Browse...  
Root directory: //Client/H\$/HC Browse...

Select a signing certificate

Current file: //Client/H\$/My Certs and WebTrader Cert/Ryan/Ryan Password.p12  
New file:  Browse...  
MyCertificate.p12 or MyPrivateKey.pfx

Send